REMARKS

The Office Action of November 1, 2006 has been carefully reviewed and considered. In response, claims 3 and 10 are amended to correct two transcription errors. Claim 16 is amended to more clearly patentably distinguish over the prior art. Claims 17-19 are canceled without prejudice.

Turning now to the substantive issues, claims 1-19 are rejected under U.S.C. 102(b) as being anticipated by *Gordziel* (U.S. 6,037,358, the '358 patent), *Chopdekar et al.* (U.S. 5,663,415, the '415 patent), or *Leiflein et al.* (U.S. 6,417,206, the '206 patent). The Examiner indicates that claims 1-19 are drawn to a manufacturing process for the conversion and incorporation of a salt or free base of an active pharmaceutical ingredient into a therapeutic liquid or semi-solid dosage form. This statement is correct but the Examiner merely quoted the preamble of independent claims 1-16, and a portion of the preamble in claim 5. It is textbook patent law that the preamble of a claim generally does not provide patentable weight when distinguishing over the prior art. (*DeGeorge v. Bernier*, 768 F2d 1318, 226 USPQ 758, 761 n.3 (Fed. Cir 1985)). The invention is then set forth following the word "comprising", "comprises" or "consisting of". The Examiner completely ignored the defined invention in independent claims 1, 5 and 16.

In claim 1, the invention comprises the steps of:

(a) dissolving the salt or free base of the active pharmaceutical ingredient in a pharmaceutically acceptable liquid in the

presence of a dispersing agent and tannic acid under stirring, to form a dispersion wherein the tannic acid component is of either a natural or synthetic source;

(b) combining the tannate salt complex of the active pharmaceutical ingredient without isolation or purification with pharmaceutically acceptable excipients to generate a therapeutic dosage form.

In claim 5, the invention comprises the steps of:

(a) dissolving the salt or free base of the active pharmaceutical ingredient in a pharmaceutically acceptable liquid in the presence of a dispersing agent and tannic acid under stirring, to form a dispersion wherein the tannic acid component is of either a natural or synthetic source;

(b) combining the tannate salt complex of the active pharmaceutical ingredient without isolation or purification with pharmaceutically acceptable excipients to generate a therapeutic dosage form.

In claim 16, as amended, the invention comprises the steps of:

dissolving the salt or free base of the pharmaceutical ingredient and tannic acid in a pharmaceutically acceptable liquid <u>in a single vessel</u> to form a dispersion; and

~~adding at least one~~ combining the dispersion without isolation and purification with pharmaceutically acceptable excipients ~~to said dispersion~~ to generate a therapeutic dosage form.

Referring now to the '358 patent, the disclosure relates to a therapeutic composition comprising pharmaceutically effective amounts of 25.0 mg phenylephrine tannate and 9.0 mg chlorpheniramine tannate. The "Background of the Invention" describes a process for preparing decongestants and antihistaminics in the form of their tannate salts by reacting the free base, with tannic acid in the presence of a volatile solvent, usually isopropanol. The reaction mixture is cooled to room temperature and then filtered, washed with isopropanol and then vacuum dried. See, col. 1, line 64 to col. 2, line 8. This is the only discussion of how the tannate salts of active ingredients are prepared.

Example 1 of the '358 patent describes the preparation of a tablet containing the combination of chlorpheniramine tannate and phenylephrine tannate using conventional techniques. Example 2 describes the preparation of a liquid suspension of tannate salts using the same two active ingredients also using conventional techniques. The tannate salts used in Examples 1 and 2 were prepared according to the techniques highlighted above in col. 1, line 63 to col. 2, line 8.

Claim 1 of the present invention defines a process of preparing an active ingredient tannate complex by dissolving the salt or free base of the active pharmaceutical

ingredient in a pharmaceutically acceptable liquid in the presence of a dispersing agent (emphasis added).... and combining the tannate salt complex of the active pharmaceutical ingredient without isolation or purification (emphasis added)....to generate a therapeutic dosage form. The '358 patent never mentions or suggests the use of a dispersing agent in the process of preparing chlorpheniramine tannate and phyenylephrine tannate. Also, the '358 patent never mentions or suggests combining chlorpheniramine tannate and phenylephrine tannate into the final dosage form without first filtering the newly formed tannates, washing with isopropanol and then vacuum drying. The '358 patent does not disclose two of the features defined in claim 1 and, consequently, the 35 U.S.C. 102(b) rejection based on anticipation cannot be maintained.

Similarly, Claim 5 contains the same two steps as claim 1, highlighted above. Accordingly, the 35 U.S.C. 102(b) rejection based on anticipation cannot be maintained.

Claim 16 has been amended to include the phrase "without isolation and purification" and, as discussed above, this concept is not disclosed in the "358 patent. Thus, the 35 U.S.C. 102(b) rejection cannot be maintained with regard to amended claim 16.

Referring now to the '415 patent, this patent discloses pure antihistamine tannate compositions obtained by a freeze-drying isolation/purification step following the tannate conversion step before the antihistamine tannate complex can be incorporated into a final dosage form.

Claims 1, 5 and 16 (as amended), all indicate that the tannate salt complex of the active pharmaceutical ingredient is incorporated into the final dosage form "without isolation and purification". Furthermore, claims 1 and 5 also recite the presence of a dispersing agent which is not disclosed or taught in any of the three cited references for the tannate conversion process. Accordingly, there is clearly no basis for the rejection of these claims under 35 U.S.C. 102(b) based on the '415 patent.

Finally, in reference to the '206 patent, this patent discloses a combination of carbetapentaine tannate, pyrilamine tannate and phenylephrine tannate as being novel. The only reference to the process for making the tannate salts for the three active ingredients is the same as that above for the '358 patent. See "Background of Invention", col. 2, lines 6-8, where the reaction mixture is cooled to room temperature and filtered, washed with isopropanol and then vacuum dried.

As discussed above, claims 1, 5 and 16 (as amended) all indicate that the tannate salt complex of the active pharmaceutical ingredient is incorporated into the final dosage form "without isolation and purification". As indicated above, claims 1 and 5 also recite the presence of a dispersing agent. Theses two elements are not disclosed or taught in any of the three cited references in the tannate conversion process. Accordingly, there is no basis for the rejection of these claims under 35 U.S.C. 102(b) based on the '206 patent.

Under 35 U.S.C. 102, the standard for lack of novelty or "anticipation" is one of strict identity. As stated by the Court of Appeals for the Federal Circuit in Hybritech, Inc.

v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1379 USPQ 81, 90 (Fed.Cir. 1986), "it is axiomatic that for prior art to anticipate under §102 it has to meet every element of the claimed invention..." As stated above, none of the three cited references, U.S. 5,663,415 (*Chopdekar et al.*), U.S. 6,037,358 (*Gordziel*) and U.S. 6,417,206 (*Leflein et al.*), disclose, suggest or teach all of the elements defined in the three independent claims 1, 5 and 16 (as amended) of the present invention.

Based on the above it has been demonstrated that claims 1-16 are patentable over the prior art and in condition for allowance. Such action is earnestly requested. The Examiner is encouraged to contact the undersigned below should he have any questions.

Respectfully submitted,

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